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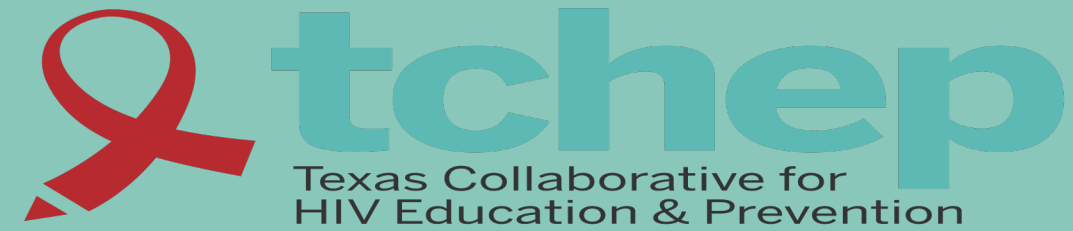


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Texas Collaborative for HIV Education and Prevention (TCHEP) Learning Series

Updates and Recommendations for Primary and Emergency Care Services



Biomedical HIV Prevention Strategies – PrEP and nPEP: Essential Tools to End the HIV Epidemic in Texas



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Texas Collaborative for HIV Education & Prevention Learning Activities:

“Biomedical HIV Prevention Strategies – PrEP and nPEP: Essential tools to end the HIV epidemic in Texas”

June 23, 2021



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Avenue 360 Health and Wellness



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Biomedical HIV Prevention Strategies – PrEP and nPEP

Essential Tools to End the HIV Epidemic in Texas

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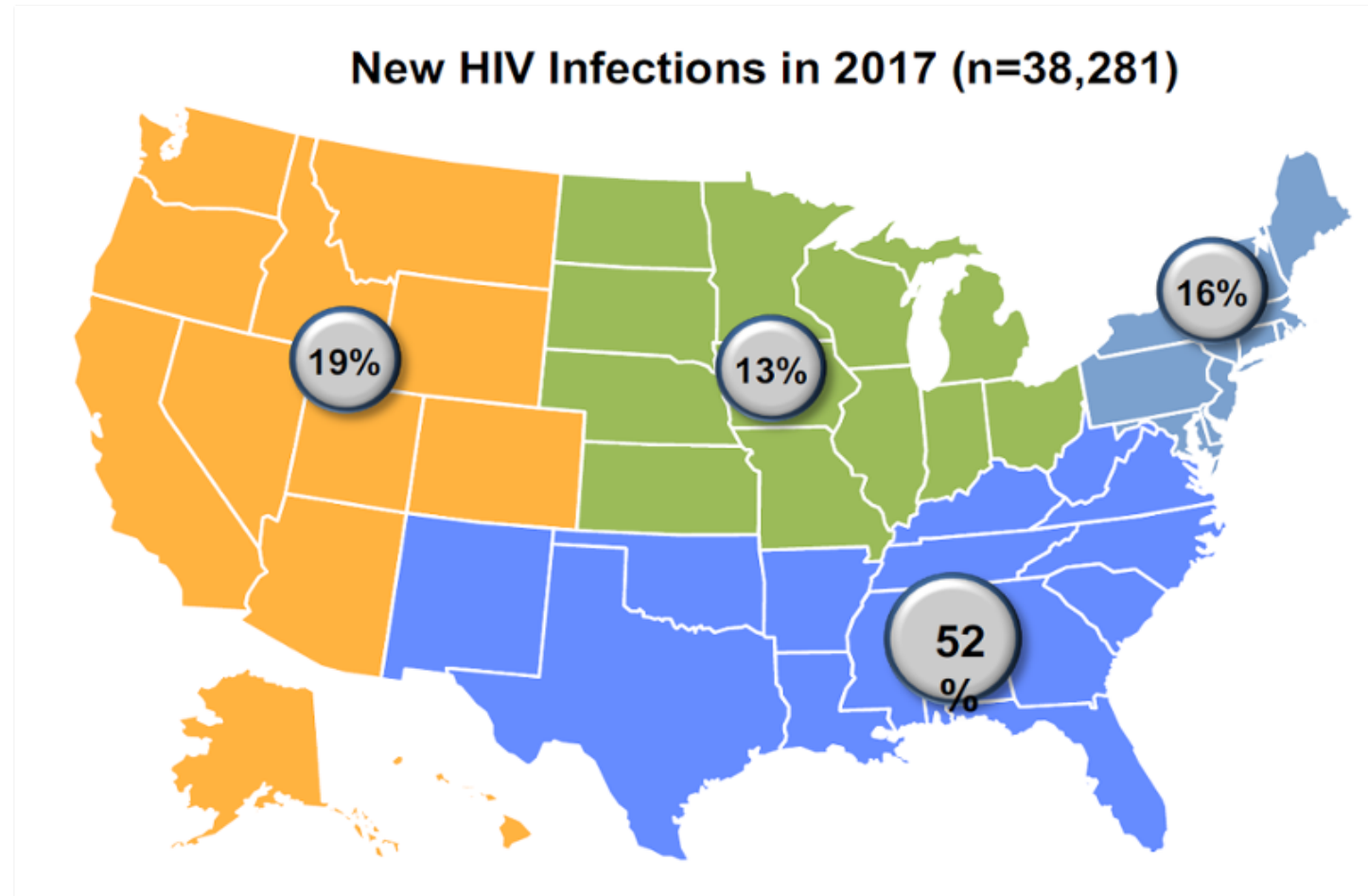
Gilead Sciences Research Scholars Program in HIV Scientific Review Committee

Member

Objectives

- Compare and contrast PrEP and nPEP and identify when each is appropriate to prescribe to prevent the acquisition of HIV.
- Summarize the treatment guidelines and resources when prescribing or referring patients for PrEP and nPEP services.

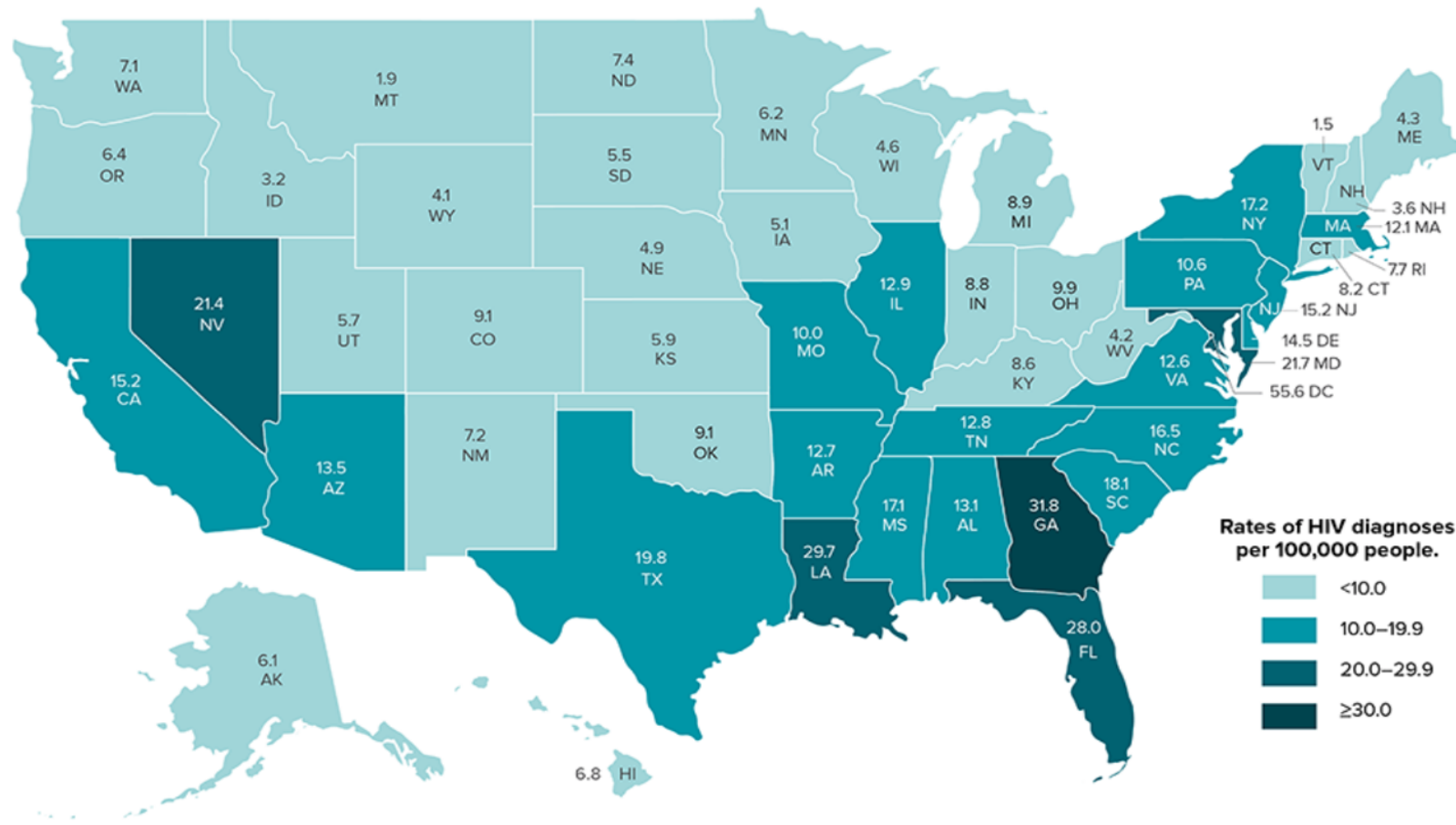
CDC 2017: Over 50% of New HIV Infections Occurred in the South



TX ranks fourth in the US in terms of number of new HIV infections.

HIV Epidemiology


Rates of HIV Diagnoses Among Adults and Adolescents in the US by State, 2016



Antiretrovirals for HIV Prevention...



- Antiretrovirals to prevent mother-to-child transmission – 1994
- Post-exposure prophylaxis (PEP)
 - Occupational settings - 1997
 - Non-occupational settings -2000
- Pre-exposure prophylaxis (PrEP) - 2010
 - Oral or topical antiretrovirals before sexual exposure
- Treatment as Prevention ((TasP)- 2011
 - Expanded treatment may decrease HIV incidence on a population level



PrEP: HIV Pre-exposure Prophylaxis



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Pre-exposure Prophylaxis (PrEP)

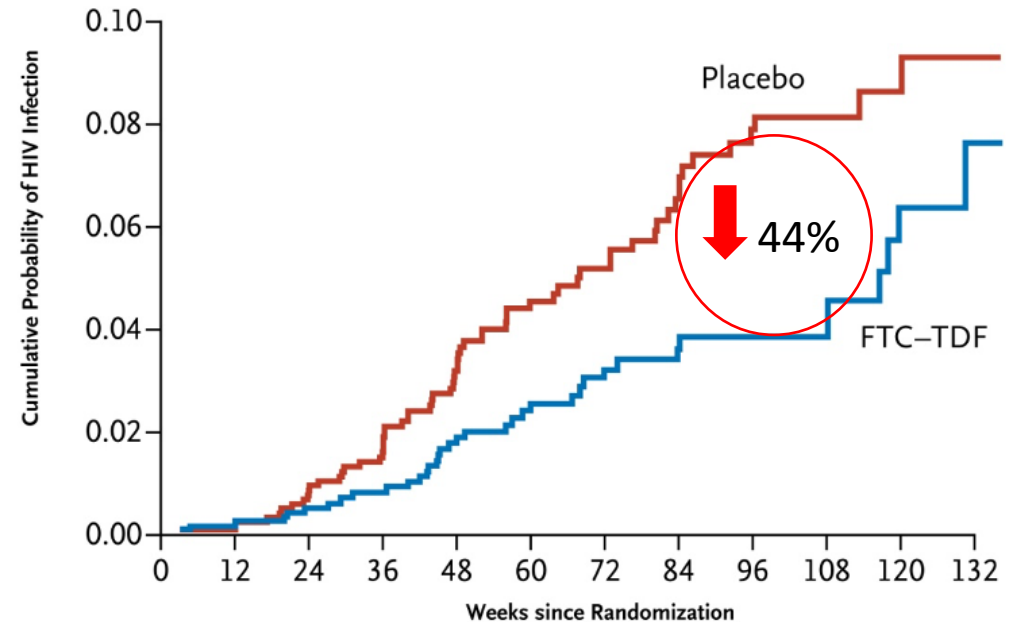
- Vulnerable people use a part of an HIV drug cocktail to prevent HIV.
- FDA approved drugs
 - Once daily tablet
 - Co-formulated tenofovir disoproxil fumarate 300 mg (TDF) and emtricitabine (FTC) 200 mg
 - Co-formulated tenofovir alafenamide and FTC (excludes women)
 -If taken perfectly 92%-100% effective



Pre-exposure Prophylaxis Initiative Trial (iPrEx)

- Oral PrEP
- RCT of 2,500 gay or bisexual men and transgender women
- Once-daily FTC-TDF or placebo
- 44% reduction in HIV incidence in the intervention group

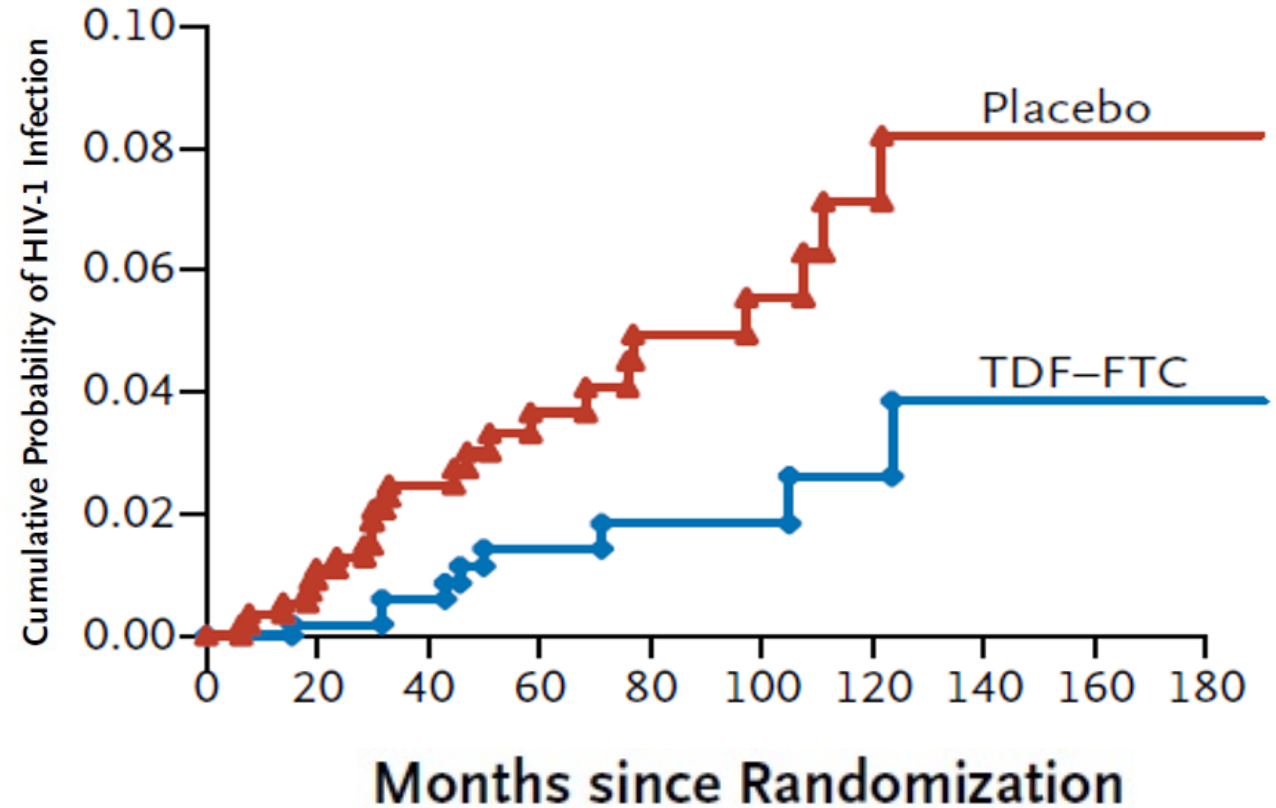
Figure 2. Kaplan–Meier Estimates of Time to HIV Infection (Modified Intention-to-Treat Population).



Oral PrEP

TDF2-CDC

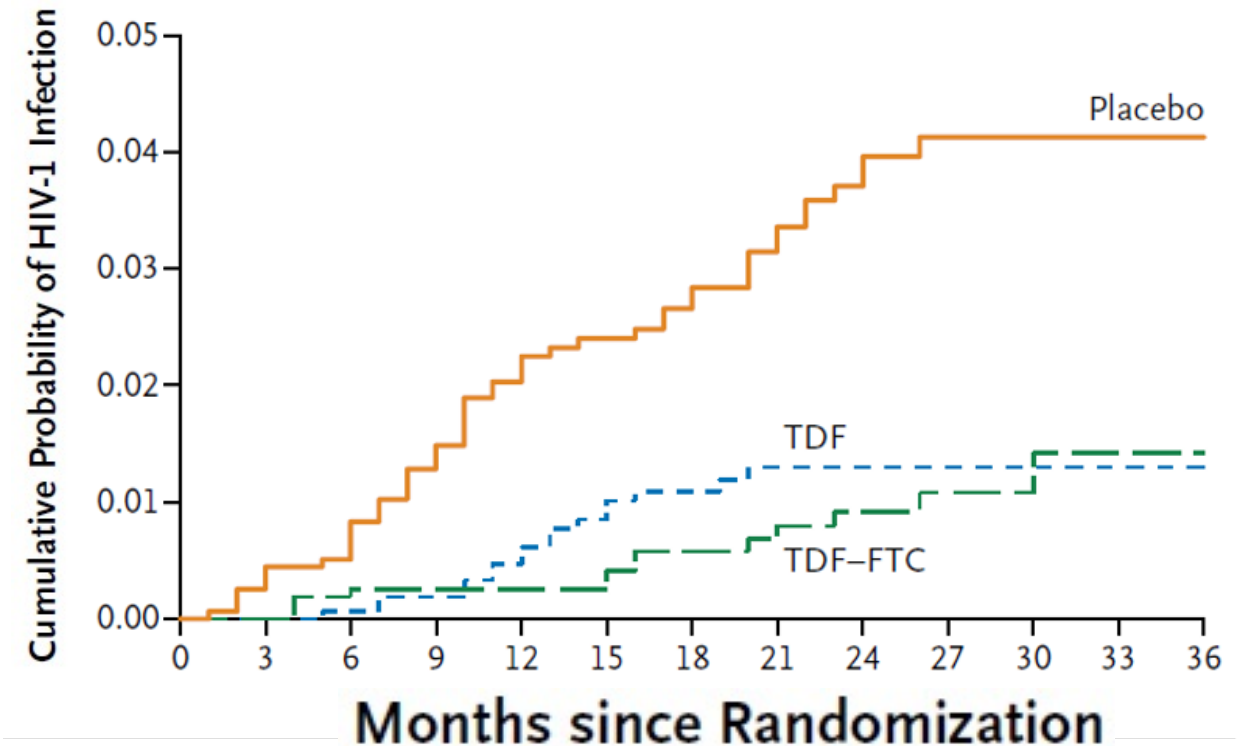
- Randomized Control Trial
- 1,200 men and women
 - Botswana
 - Daily oral
 - FTC-TDF vs. placebo
- 63% reduction in the risk of HIV acquisition



Oral PrEP

Partners PrEP

- 4,758 HIV sero-discordant heterosexual couples
 - Kenya & Uganda
 - TDF vs. FTC-TDF vs. placebo
 - Pregnancy rate was high (10.3 per 100 person –years) with no difference between groups



TDF → 62% fewer infections
FTC-TDF → 73% fewer infections

Oral PrEP

Pre-exposure Prophylaxis Initiative Trial (iPrEx)



Import of Adherence

- Case-control sub-group analysis
 - Patients with detectable free FTC, TDF, or their intracellular metabolites
 - → 92% decreased risk of becoming infected

How long until it takes effect?



Oral PrEP maximum intracellular concentration

- Cervicovaginal tissue: 20 days
- Blood: 20 days
- Rectal tissue: 7 days

PrEP Failure/Drug Resistance



- **iPrEx:** 10 participants already HIV-infected at the time of enrollment in the window period of acute HIV
 - Most were in the placebo arm
 - 2 randomized to FTC-TDF ? transmitted or newly-evolved resistance
- PrEP users with multiple mutations upon seroconversion

Drug Safety Considerations

- Nausea and mild inadvertent weight loss
 - in about 1-2% of the study participants
- Renal insufficiency
- 1% BMD loss at the total hip and femoral neck
 - rate of bone fractures was no different
- **FTC/TAF efficacy – trade name Descovy (2020)**
 - Among MSM and trans women
 - Less impact on bone and kidney

Risk Compensation

- Sexual disinhibition and reduction in use of condoms as an adjunct safety measure
- In clinical trials trend toward **decreased** sexual risk behavior
 - **Self-report, clinical trial setting, coupled with behavioral interventions**
- In non-trial settings, risk-taking behavior seasonal and influenced by personal, psychosocial and health-related features.

CDC Guidelines, 2017

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Persons Who Inject Drugs
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI [‡] High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI [‡] High number of sex partners History of inconsistent or no condom use Commercial sex work In high HIV prevalence area or network	HIV-positive injecting partner Sharing injection equipment
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 3-6 months, test for bacterial STIs		
	Do oral/rectal STI testing	For women, assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

STI: sexually transmitted infection

United States Preventive Services Task Force

Final Recommendation Statement for PrEP

- PrEP is of substantial benefit in decreasing the risk of HIV infection in persons at high risk of HIV acquisition

Sexually Active MSM
(plus 1 of the following)

Serodiscordant
sex partner

Inconsistent use of condoms during
receptive/insertive anal sex

STI with syphilis, gonorrhea, or
chlamydia in past 6 months

Heterosexual Men/Women
(plus 1 of the following)

Serodiscordant
sex partner

Inconsistent use of condoms during
sex with partner of unknown HIV
status or at high risk for HIV
acquisition

STI with syphilis or gonorrhea
in past 6 months

PWIDs
(plus 1 of the following)

Shared use of
drug injection equipment

Risk of sexual acquisition of HIV

PrEP Implementation

Before initiating PrEP:

- Determine eligibility
- Document negative HIV test
- Test for acute HIV infection
 - Symptomatic
 - Reports unprotected sex with an HIV-positive person in the preceding month

Ongoing Assessment:

- Link HIV-infected sexual partners to care
- Monitor renal function
- Screen for hepatitis B infection
 - Vaccinate or treat.
- Follow-up every 3 months
 - HIV testing – HIV Ab or 4th gen Ag/Ab
 - Adherence and Risk reduction counseling

PrEP Implementation Cont.

Ongoing Assessment:

- Screen and treat STIs
- Risk-reduction counseling
- Condoms
- PrEP medication—adherence counseling

Potential PrEP Users:

- Condomless anal sex with HIV status unknown partner(s)
- Known partner who has HIV
 - Indicate that they do not always use condoms
 - HIV + partner's viral load not consistently undetectable
- Recent history of transactional sex
- Bacterial sexually transmitted infection
- Inconsistent or non-condom use
- Injection drug use, alcohol dependence
- Incarceration
- High risk partner
- High prevalence area or network

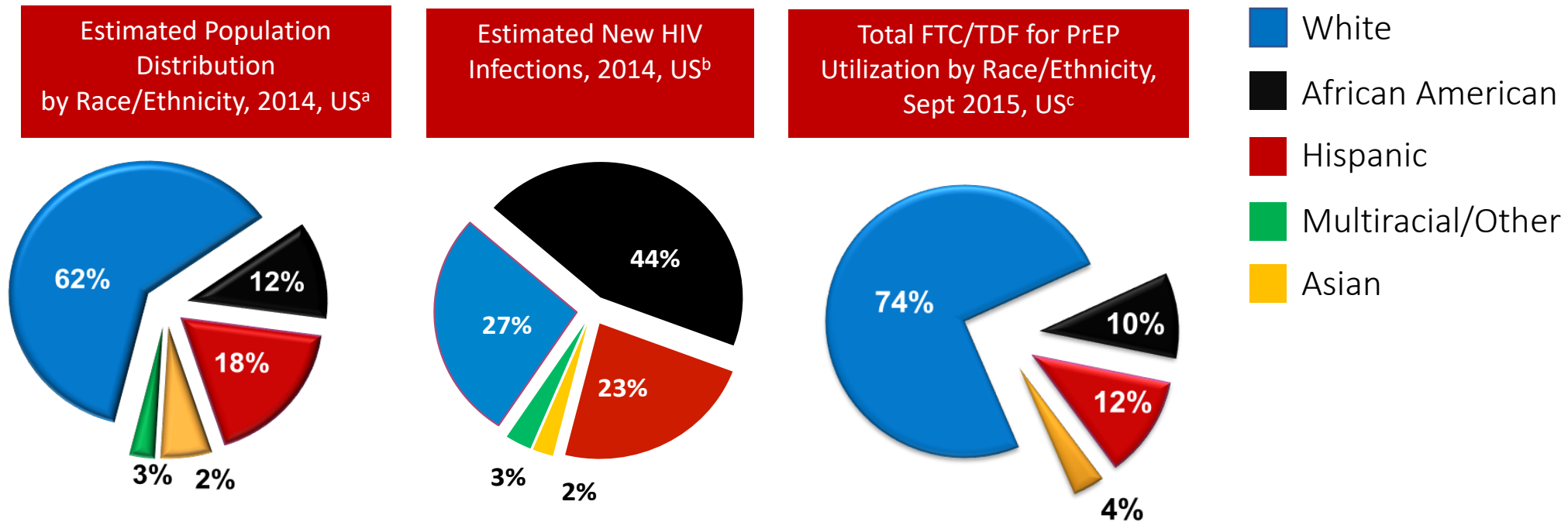
Risk Groups

TABLE 2. Estimated percentages and numbers of adults with indications for preexposure prophylaxis (PrEP), by transmission risk group — United States, 2015

Transmission risk group	% with PrEP indications*	Estimated no.	(95% CI)
Men who have sex with men, aged 18–59 yrs [†]	24.7	492,000	(212,000–772,000)
Adults who inject drugs, aged ≥18 yrs [§]	18.5	115,000	(45,000–185,000)
Heterosexually active adults, aged 18–59 yrs [¶]	0.4	624,000	(404,000–846,000)
Men**	0.2	157,000	(62,000–252,000)
Women	0.6	468,000	(274,000–662,000)
Total	—	1,232,000	(661,000–1,803,000)

Disparities in PrEP Utilization


People of color comprise a disproportionate number of new HIV infections in the US, yet have limited uptake of HIV pre-exposure prophylaxis (PrEP).



PrEP use among AA and Hispanics is low relative to the rate of new HIV infections

Drivers of PrEP Uptake

- Address poor access to health care in the most at-risk communities
- Enhance limited risk awareness among many vulnerable populations
- Enhance limited HIV prevention education
- Consider alternative delivery systems such as telemedicine
- Consider partnering with community health workers or patient navigators



nPEP: non-occupational Post-exposure Prophylaxis



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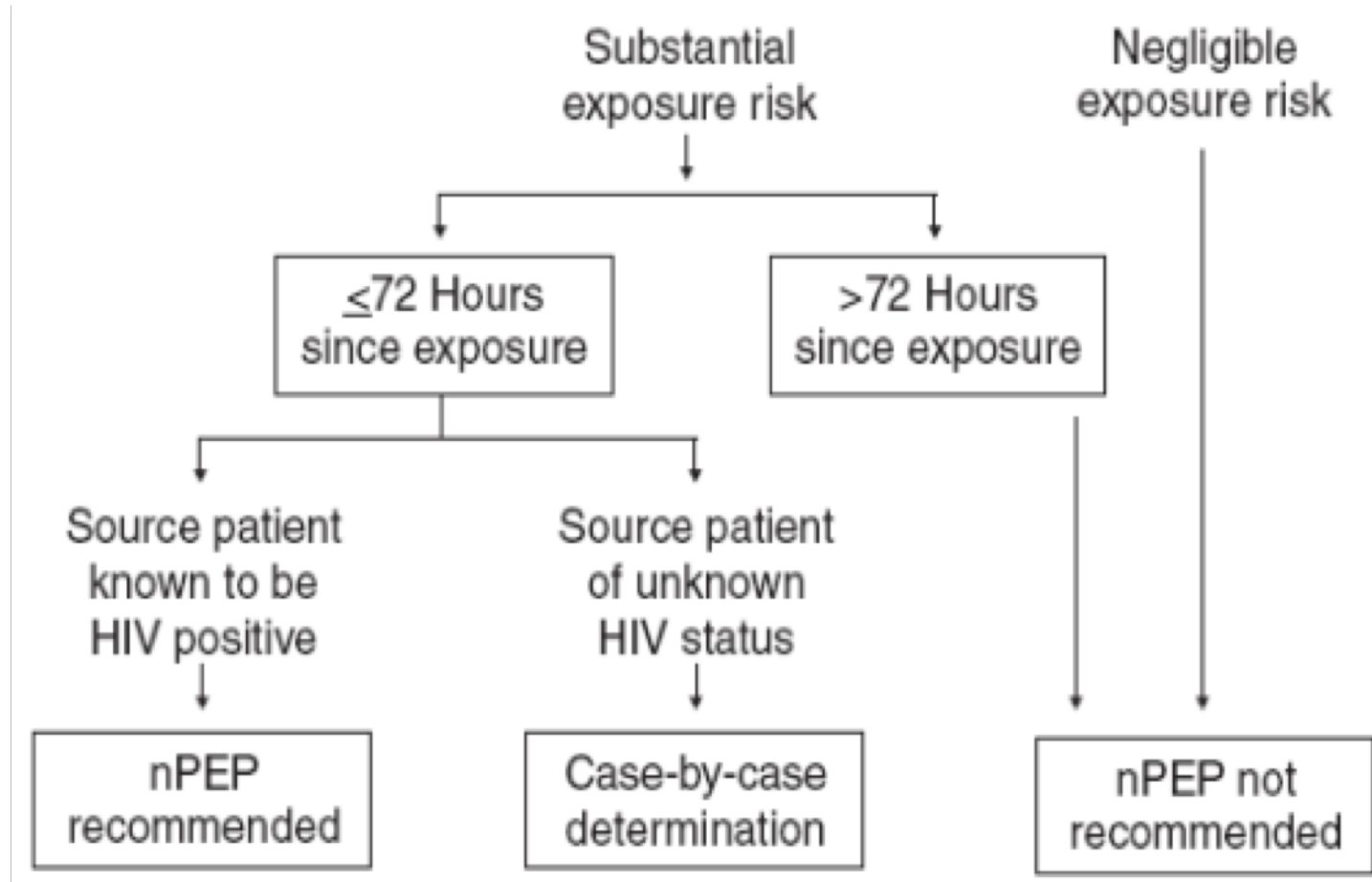


nPEP Process

- **Obtain HIV test**
 - Rapid test ideal
 - Otherwise don't wait... time is ticking
- **Patient follow-up**
 - Medication tolerance in two weeks
 - Repeat HIV testing at end of 4 weeks and 3 months later
- **Screen for other STDs**



Post-exposure prophylaxis



Earlier the start the better

- **Methods**

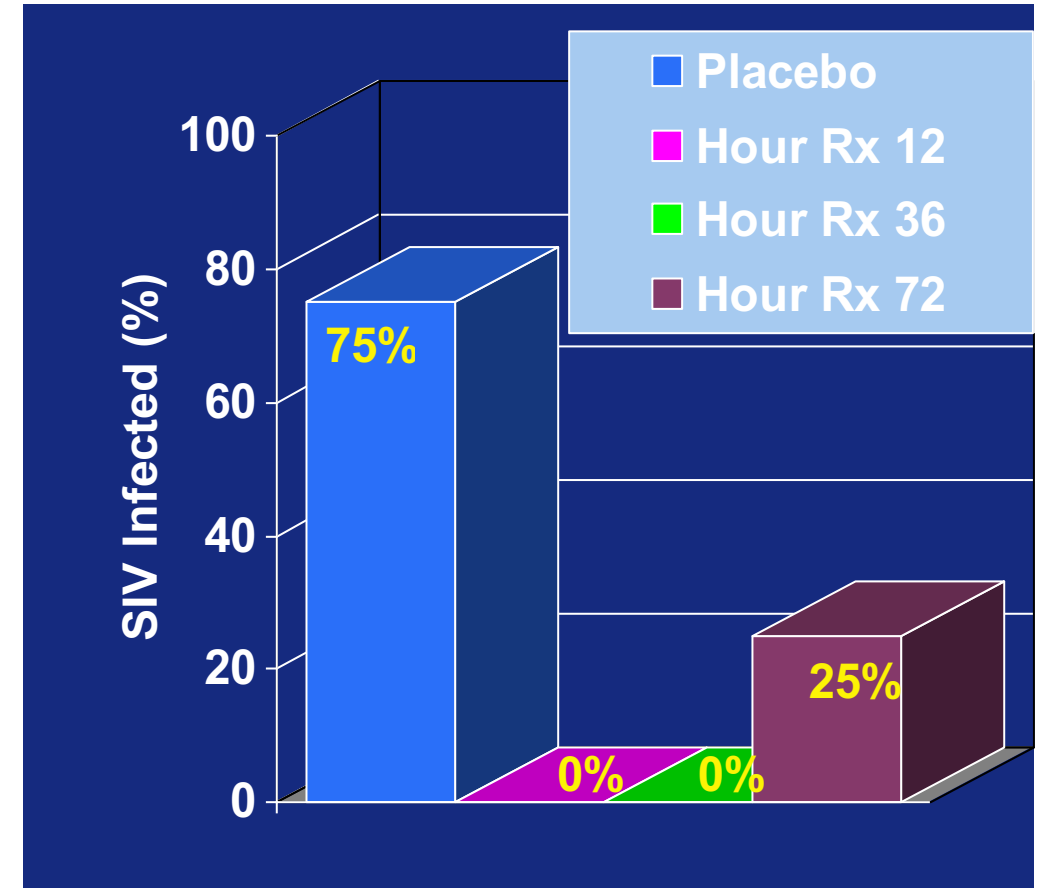
- HIV-2 inoculated intra-vaginally
- N = 16 female macaques

- **Regimens**

- Control vs. Tenofovir regimens
- PEP started @ 12, 36, or 72 h
- PEP Rx for 28d

- **Results**

- No transmissions if started before 72 hrs.
- At 72 hrs 25% infected.



Longer treatment better

- **Methods**

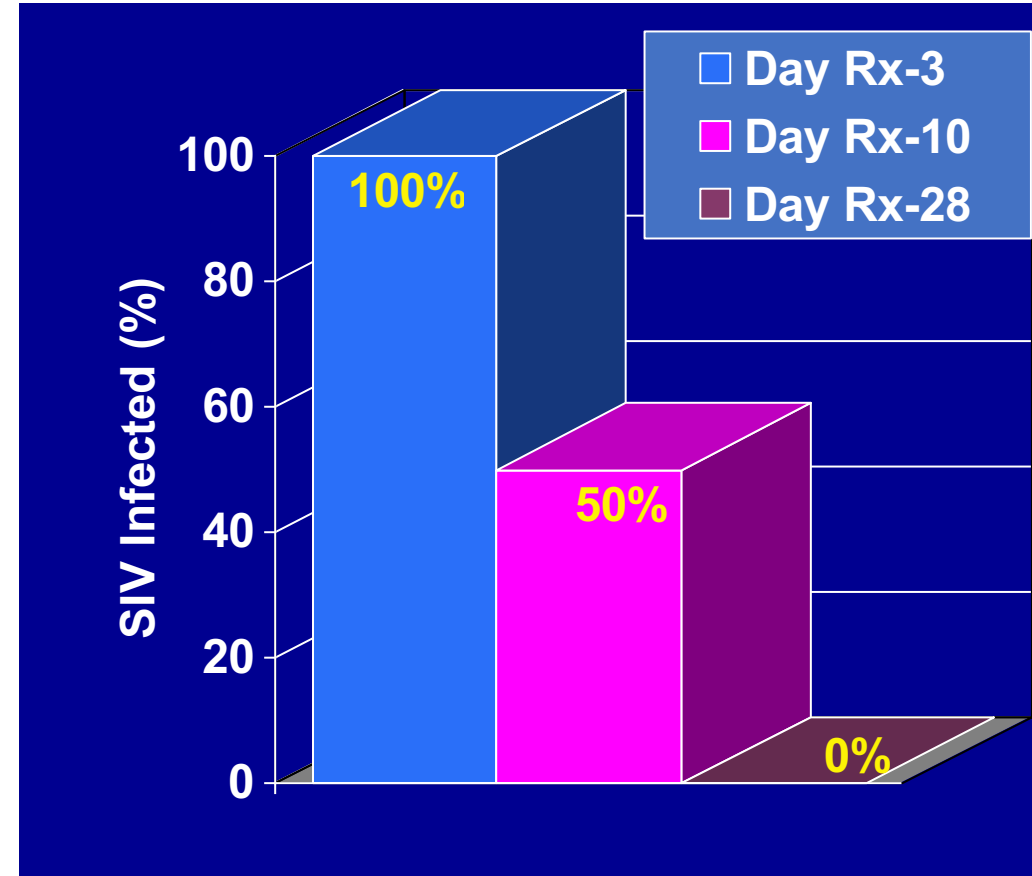
- SIV inoculated IV
- N = 24 macaques

- **Regimens**

- Control vs. Tenofovir
- Start at 24, 48, or 72h
- Treat for 3, 10, or 28d

- **Results**

- 28 days works, less may not



nPEP to PrEP transition

- Patients who request PrEP and also have had a possible sexual or injection drug-related HIV exposure in the prior 72 hours (i.e., are within the recommended window to start nPEP)
- Patients who request repeated courses of nPEP, particularly over a relatively recent period (e.g., more than twice during the past 6 months)
- At end of nPEP regimen:
 - Repeat a rapid HIV test (ideally with a fourth-generation antigen/antibody assay)
 - assess for signs and symptoms of acute HIV infection.

nPEP to PrEP Follow-up

- If the rapid HIV test is **positive** or suspicion exists of possible acute HIV infection,
 - draw blood for confirmatory testing
 - continue a 3-drug nPEP regimen pending confirmation
- If the rapid HIV test is **negative** **and** no signs or symptoms of acute infection exist:
 - Stop the third medication in nPEP regimen
 - Continue TDF/FTC daily as Prep
 - Complete any PrEP baseline laboratory testing not already performed as part of nPEP testing.
 - Provide adherence and risk-reduction counseling.



Thank You!



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CommUnityCare Health Centers



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Sexual Health Assessments Pathways to Prevention

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Disclosures

- **None**

Learning Objectives

- Demonstrate how a sexual health assessment can be integrated into primary care services
- Discuss the importance of sexual health assessments in identifying patients at risk of acquiring HIV and when it is appropriate to prescribe or refer patients for PrEP or nPEP

Glossary of Acronyms

- **PrEP** – Pre-exposure prophylaxis
- **nPEP** – nonoccupational post-exposure prophylaxis
- **PLWH** – People Living with HIV
- **MSM** – Men who have sex with men
- **PWID** – People who inject drugs



Sexual Health Assessments

Why asking about sexual health in primary care settings matters



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Defining Sexual Health

- World Health Organization
 - Sexual health is a state of physical, emotional, mental and social well-being in relation to sexuality; it is **not merely the absence of disease**, dysfunction or infirmity.
 - Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence

Scenarios in Sexual Health

- Myranda (she/her) is a 23 year old cisgender woman who comes to the clinic complaining of right lower abdomen pain ongoing for 2 weeks. She is mildly tender in the lower quadrants of her abdomen and notices burning with urination. She was asked whether she was single or married. No other questions were solicited about her sexual health. A pregnancy test is negative.
- Lyle (he/him) is a 36 year old cisgender male who comes in requesting routine STI testing from his PCP. He doesn't know his provider well and is often reserved during these clinic visits. He completes a routine sexual health assessment as part of his intake process given the reason cited for his visit.

Scenarios in Sexual Health

- Myranda is treated for a urinary tract infection with oral antibiotics and sent home. Four days later she returns complaining of vaginal discharge. Her partner tested positive for chlamydia a few months back but she never got treated. Based on your history and exam you decide to treat the patient for subacute pelvic inflammatory disease (PID)
- Lyle's answers to his sexual health assessment notes that he is sexually active with men only and engages in receptive anal sex and receptive oral sex. Hence you advise him to receive triple site testing for GC/CT. His answers also suggest he is interested in learning more about PrEP. After a conversation you agree to start same day PrEP

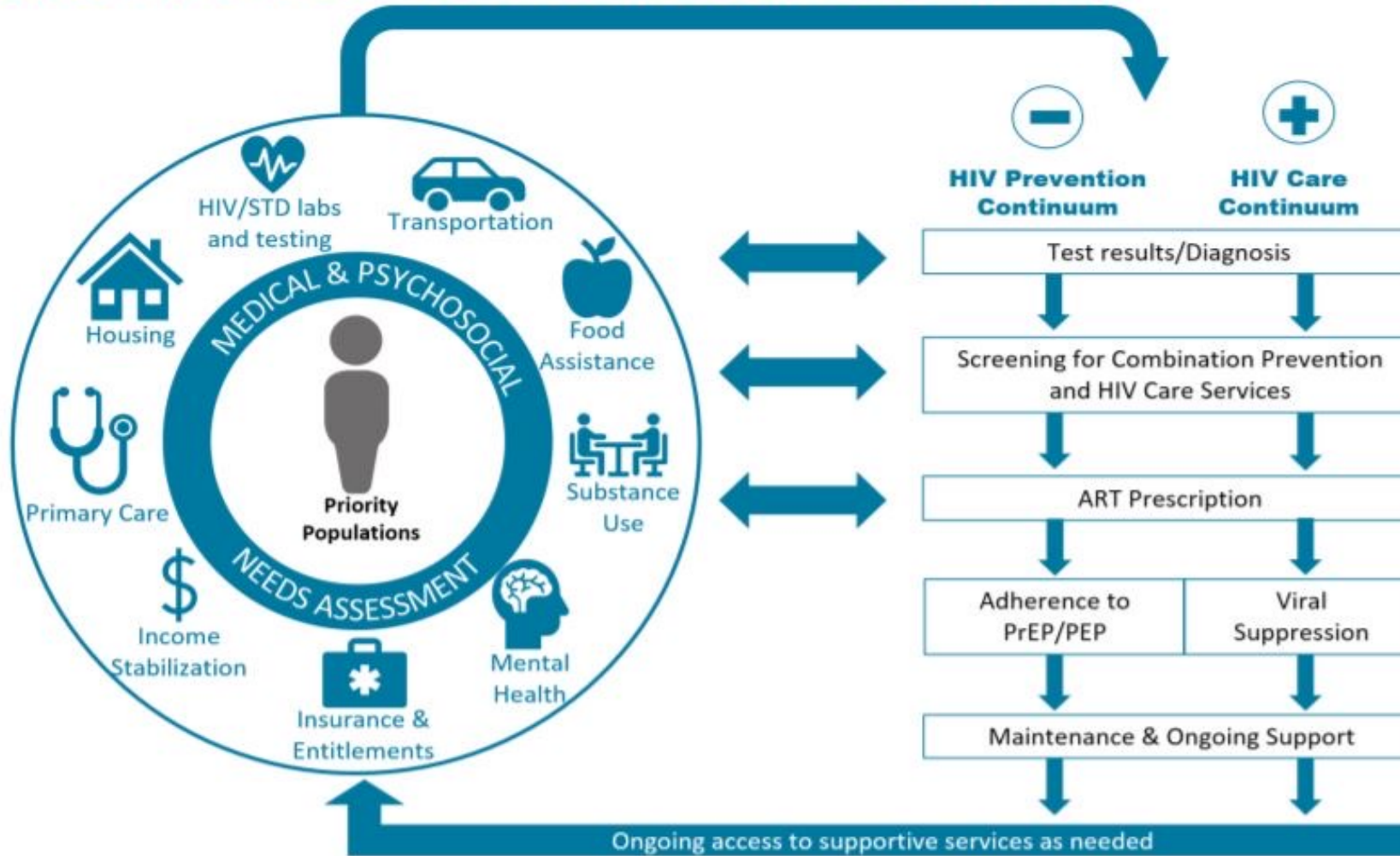
Scenarios in Sexual Health

- Miranda returns to the office 3 days later feeling clinically improved. Her GC/CT NAAT testing did indeed result in +CT test. She returns again 3 months later for repeat STI testing.
- Lyle receives a call that his rectal NAAT test resulted positive for gonorrhea. He returns to clinic for appropriate treatment. He affirms that he has been taking his PrEP daily.

Sexual Health Assessments

- Array of questions administered either via conversation or self-report documentation asking about sexual practices, partners, STI's and addressing any concerns related to sexual health
- Gateway into more comprehensive sexual health services
 - Status neutral care continuum
- Can be routinely implemented in primary care

STATUS NEUTRAL AT THE INDIVIDUAL LEVEL



Why Ask About Sexual Health?

- Fundamental to overall health
- Opportunity for health promotion
- Guide testing or treatment
- PrEP
- nPEP
- Cultivate trust, rapport and therapeutic alliance
- Destigmatizing and demystifying

Recommendation Summary

Population	Recommendation	Grade
Sexually active adolescents and adults at increased risk	<p>The USPSTF recommends behavioral counseling for all sexually active adolescents and for adults who are at increased risk for sexually transmitted infections (STIs).</p> <p>See the Practice Considerations section for more information on populations at increased risk for acquiring STIs.</p>	B

Table 2: Recommended preventive sexual health services for various patient populations (including those who are transgender)

	Females				Males			
	Teens (13-17)	Adults (18-64)	Older adults (65+)	Pregnant	Teens (13-17)	Adults (18-64)	Older adults (65+)	MSM (all ages)
Counseling - STIs	✓ ^a	✓ ^b	✓ ^b	✓ ^{a,b}	✓ ^a	✓ ^b	✓ ^b	✓ ^{a,b}
Contraceptive counseling	✓	✓		✓	✓ ^c	✓ ^c	✓ ^c	
Cervical cancer screening*		✓ ^d	✓ ^d	✓ ^d				
Chlamydia screening	✓ ^e	✓ ^e	✓ ^e	✓ ^e	✓ ^f	✓ ^f		✓ ^g
Gonorrhea screening	✓ ^e	✓ ^e	✓ ^e	✓ ^e				✓ ^h
HIV testing	✓	✓	✓ ^b	✓	✓	✓	✓ ^b	✓
Syphilis screening	✓ ⁱ	✓ ⁱ	✓ ⁱ	✓	✓ ⁱ	✓ ⁱ	✓ ⁱ	✓
Hepatitis B screening	✓ ^j	✓ ^j	✓ ^j	✓	✓ ^j	✓ ^j	✓ ^j	✓
Hepatitis C screening		✓ ^{k,l}	✓ ^{k,l}	✓ ^k		✓ ^{k,l}	✓ ^{k,l}	✓ ^{k,l}
Hepatitis A vaccine	✓	✓ ^m	✓ ^m	✓ ^m	✓	✓ ^m	✓ ^m	✓
Hepatitis B vaccine	✓	✓ ⁿ	✓ ⁿ	✓ ⁿ	✓	✓ ⁿ	✓ ⁿ	✓
HPV vaccine	✓	✓ ^o			✓	✓ ^o		✓ ^o

Sexual Health Equity

- Only about 10% of eligible people actually receiving PrEP
- Bridge disparities in PrEP access
 - Racial disparities in access
 - Gender disparities
- Risk stratification tools are imperfect
- Self perceived level of risk < objective risk

Sexual Health Assessments + PrEP

- Assessments may identify some who may derive benefit from PrEP
 - MSM
 - Condomless sex
 - History of STI recently
- Don't use assessments to exclude from PrEP
- Avoid conversations about “risk” and instead opt for less stigmatizing terminology about “vulnerability to HIV”
- Door to broader PrEP literacy

[1] Vazquez, E. Say Goodbye to Risk. The BodyPro. <https://www.thebodypro.com/article/say-goodbye-to-risk>

[2] Blumenthal J, Jain S, Mulvihill E, et al. Perceived Versus Calculated HIV Risk: Implications for Pre-exposure Prophylaxis Uptake in a Randomized Trial of Men Who Have Sex With Men. *J Acquir Immune Defic Syndr*. 2019;80(2):e23-e29. doi:10.1097/QAI.0000000000001888



Sexual Health Integration

A How to Guide for Integrating Sexual Health Assessments into Primary Care



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Background on Sexual Health Assessments at CommUnityCare

- Started as a supportive document to inform clinical care rendered by our STI nurse at our HIV primary care hub
- Expanded to primary care settings and urgent care / walk-in settings to help identify those who may benefit from PrEP / nPEP
- Routine part of PrEP or sexual health related visits

Sexual Health Assessment at CommUnityCare

- Administered to our patients at:
 - HIV Primary Care Site
 - Walk in Sites
 - PrEP visits
 - Piloting it with select primary care providers within our FQHC
- Utility
 - Guides clinical care for our STI nurse or other providers
 - PrEP / nPEP navigation
 - Contraception or family planning navigation
- Tool for our providers to normalize conversations about sexual health in primary care
- **Our Goal:** Embed our assessment tool into the EMR for universal access for staff and virtual use by patients. Best practice advisory for at least annual use for patients.

Sexual Health Questionnaire

Your sexual health is important to your overall health. These questions and answers are kept confidential and are an important part of the care you receive in your clinic. Please read and answer the following questions to the best of your ability.

1. In the last 12 months have you been sexually active? This includes oral sex, anal sex, or sex involving genitals (Check one)

- ☐ Yes
- ☐ No

2. In the past 12 months, how many sexual partners have you had? (Check one)

- ☐ None
- ☐ One
- ☐ More than one

3. With any sexual encounter how often do you use any form of barrier protection like condoms? (circle one)

- ☐ All of the time
- ☐ Some of the time
- ☐ None of the Time
- ☐ Not applicable

4. Which part/s of your body do you use during sex? (Check all that apply)

- ☐ Penis
- ☐ Vagina/Front hole
- ☐ Anus/Back hole
- ☐ Mouth/Throat
- ☐ Other (e.g. digital/finger in the vagina or anus) _____

5. Which part/s of their bodies do your partners use during sex? (Check all that apply)

- ☐ Penis
- ☐ Vagina/Front hole
- ☐ Anus/Back hole
- ☐ Mouth/Throat
- ☐ Other (e.g. digital/finger in the vagina or anus) _____

6. Have you ever tested positive for any of the following sexually transmitted infections (STI's)?
(Check all that apply)

- ☐ Chlamydia
- ☐ Gonorrhea
- ☐ Syphilis
- ☐ Genital warts / HPV
- ☐ HIV
- ☐ Herpes
- ☐ I never tested positive for an STI

7. Are you concerned you might have a sexually transmitted infection today? (Check one)

- ☐ Yes
- ☐ No

8. Are you aware of any partners who were recently diagnosed with a sexually transmitted infection? (Check one)

- ☐ Yes
- ☐ No

9. Are you concerned you might have been exposed to HIV recently? (Check one)

- ☐ Yes
- ☐ No

10. Are you interested in learning more about pre-exposure prophylaxis for HIV prevention (PrEP)?

- ☐ Yes
- ☐ No

11. Are you experiencing any of the following symptoms: (Check all that apply)

- ☐ Fevers
- ☐ Muscle aches or body aches
- ☐ Sore throat
- ☐ New spots or ulcers or warts anywhere on the body
- ☐ Burning with urination
- ☐ Discharge from the penis/vagina/front hole
- ☐ Discharge from the rectum or rectal bleeding
- ☐ Rectal pain
- ☐ New rash
- ☐ I am not experiencing any of these symptoms

Core Dimensions of Sexual Health Assessments

- Face to face verbal assessment vs what to include in self reported assessment
- Attention to inclusive terminology
- The 5 P's

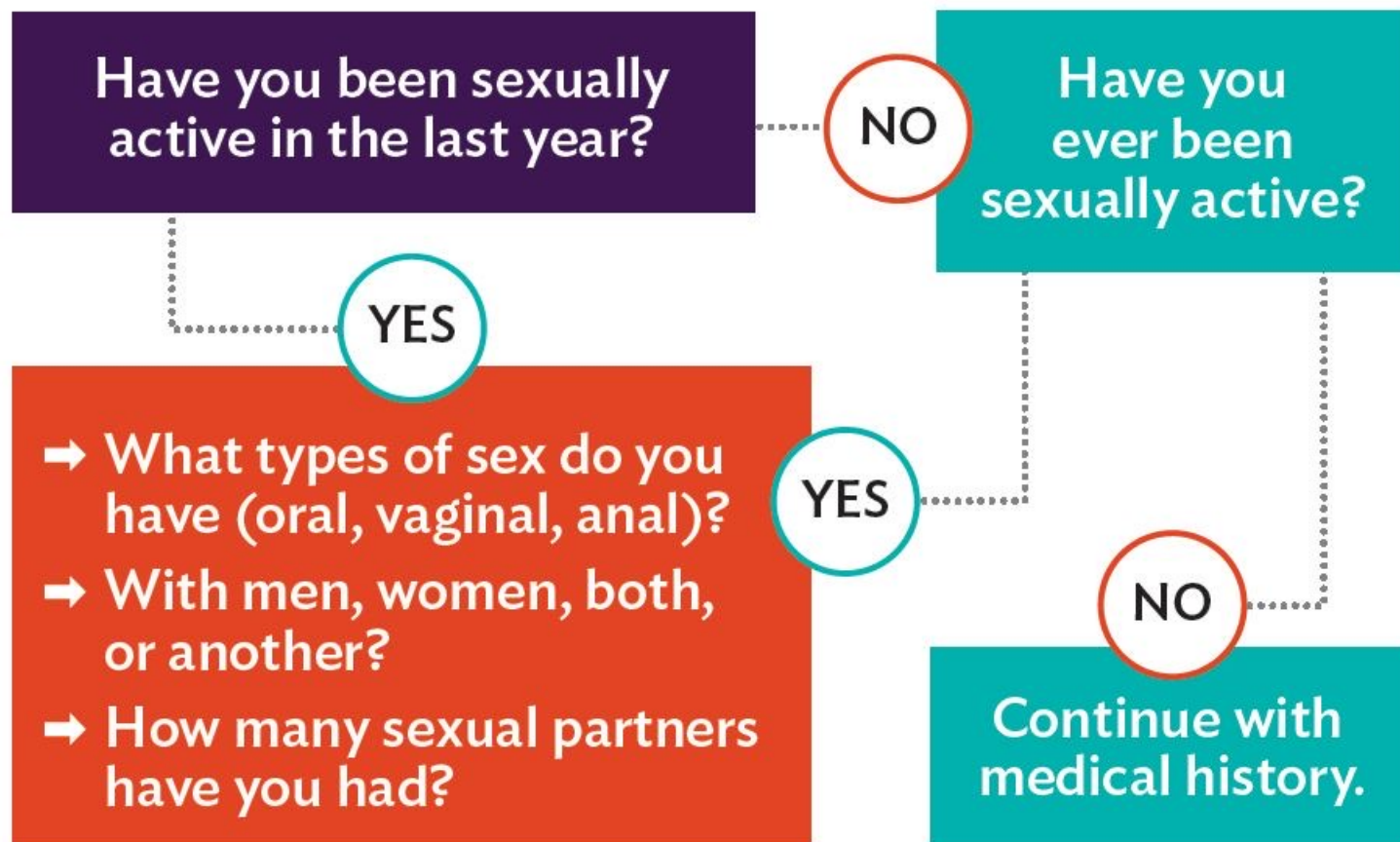
The 5 P's

- Partners
- Practices
- Past history of STIs
- Protection (condomless)
- Pregnancy prevention (reproductive life plan)
- Plus!
 - Pleasure, problems, pride

A Conversation Starter

- Practice transition statements
- Use non-judgmental, normalizing language
 - “People come into the office every day requesting routine STI testing. I think that sexual health is a very important part of our overall health for everyone”
- Ubiquity statements
- Open ended questions
- Affirm people and build them up

“I’m going to ask you a few questions about your sexual health. Since sexual health is very important to overall health, I ask all my patients these questions. If you’re uncomfortable answering any of these, just let me know, and we’ll move on. To begin, what questions or sexual concerns would you like to discuss today?”



Implementation

- Workflow design and administration of assessment
- Pairing with cultural humility staff development training
- EMR integration

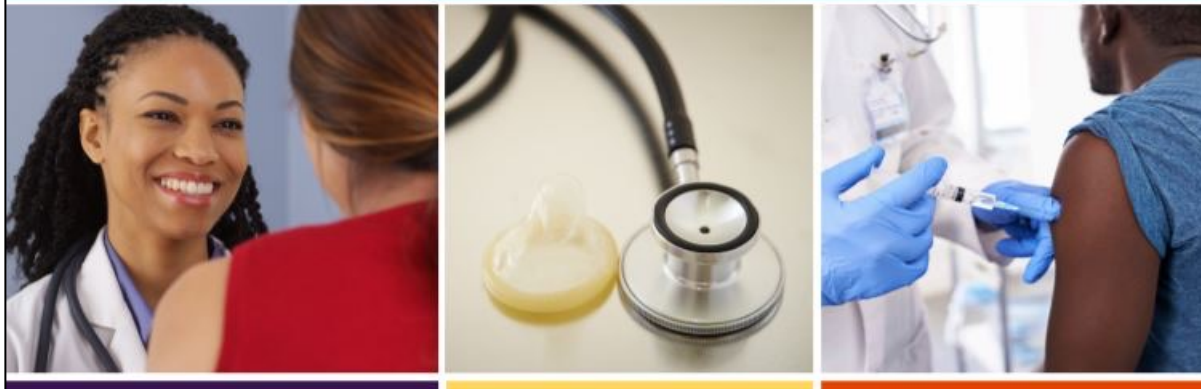
Implementation

- Buy in from care teams
- Framing the tool as time saving
- Internal champions
- Cultivate central repository for organization specific information related to sexual health
 - Navigation tools are essential

Setting the Tone & Cultivating an Inclusive Environment

- Physical spaces convey messages + representation matters
 - Create inclusive spaces
- Staff and workforce development
 - Front of the office to the back
- Educational and prevention materials

Sexual Health and Your Patients: A Provider's Guide





That's all, folks!

Any Questions?



TEXAS
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Texas Department of State
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Thank you!